K041240

JUN - 2 2004

510(k) Summary

Prepared: May 7, 2004

Establishment's Name, Address, Telephone and Contact Person:

Establishment Address: Fertility Solutions, Inc.
13000 Shaker Blvd.
Cleveland, OH 44120
phone: 216-491-0030

Establishment Registration Number: 3003750510

Contact Person: Susan A. Rothmann, PhD, President

Classification Name: Semen Analysis Quality Control, Assayed and Unassayed

Common Name: Sperm Count Quality Control, Post-vasectomy Quality Control

Proprietary Name: AQC™ Sperm Count Quality Control, AQC™ Post-vasectomy Quality Control, AQC™ Sperm Count Proficiency Challenge, AQC™ Post-vasectomy Proficiency Challenge

Classification: Proposed Class II
Product Code: NRF
Regulation Number: CFR 864.8625, Hematology

510(k) Summary

Predicate Devices:

The Fertility Solutions, Inc. AQC™ Sperm Count Quality Controls and AQC™ Post-vasectomy Quality Control are substantially equivalent to other such controls in general use such as:

- The Para Tech Plus Retics manufactured by Streck Laboratories, which is supplied as a liquid suspension of stabilized human red blood cells, human white blood cells, simulated human platelets, and simulated human reticulocytes.
  510K# K993825
- The Synovialscopics Control sold by Quantimetrix Corp., which is supplied in two levels as a liquid human source matrix to which stabilized human red blood cells and human white blood cells, other chemicals and non-protein materials have been added by the manufacturer.
  510K# K010598
- The R&D Body Fluid Control sold by R&D Systems, Inc., which is supplied in two levels as a liquid containing stabilized human red blood cells and human white blood cells, simulating cells and body fluids in morphology and count.
  510K# K020229
- The 81JPD Hematology Control sold by R&D Systems, Inc., which is supplied in three levels as a plasma-like liquid containing human erythrocytes, mammalian leukocytes, mammalian platelets, and other chemicals and non-protein materials have been added by the manufacturer.
  510K# K010409

Description:

AQC™ Sperm Count and AQC™ Post-Vasectomy Quality Controls are supplied in two levels, 0.3mL per vial. AQC™ Sperm Count and AQC™ Post-Vasectomy Proficiency Challenges are supplied in two levels, 0.15mL per vial. Each control is a ready-to-use liquid requiring no reconstitution or dilution. The liquid is prepared in a solution fortified to target levels with purified chemicals and stabilized human sperm cells and semen. Preservatives, including formalin, have been added to inhibit microbial growth and inactivate potential infectious agents.

Intended Use:

The AQC™ Sperm Count and AQC™ Post-vasectomy Quality Controls are intended for monitoring sperm counts performed either manually using commercially available counting chambers or using computer assisted semen analysis (CASA) instruments. The AQC™ Sperm Count and AQC™ Post-vasectomy Quality Controls are intended for use as Quality Control materials having known sperm concentrations. Daily monitoring of the control values establishes intralaboratory parameters for accuracy and precision of the cell counting methods. These products are also available for external laboratory quality control and proficiency testing and as such are sold under the proprietary trade names, AQC™ Sperm Count and AQC™ Post-Vasectomy Proficiency Challenges.

510(k) Summary

Technological Characteristics Compared to Predicate Devices:
The AQC™ Sperm Count and AQC™ Post-vasectomy Quality Control products employ liquid human semen matrix and a stabilized human sperm cell constituent formulation substantially equivalent to the predicate devices listed above. The predicate devices use a liquid human protein matrix containing human cells and proteins. The AQC™ Sperm Count and AQC™ Post-vasectomy Quality Controls also have similar storage and stability requirements as the predicate devices.

Performance Characteristics:
The overall shelf life of the AQC™ Sperm Count and AQC™ Post-vasectomy Quality Controls were tested in real time by storing multiple lots of the control at 2-8°C for 1 and 2 years. Sperm sample concentration in the control samples was determined using manual microscopy and sperm counting chambers at day 0 and at 30 day intervals up to 2 years. A total of 10 samples from each lot were counted at each interval. The failure criteria for stability for the recovery of cell counts for sperm cells was set as an increase or decrease of greater than 2 Standard Deviations from the mean of the original cell counts.

The closed vial stability for this product when stored at 2-8°C is 1 year. Real time testing was used to determine the closed vial refrigerated shelf life. To test the real time stability of the unopened control, vials were held at refrigerated temperature for 1 year without opening. Cell counts were compared to initial cell counts and cell counts of vials of a second lot which had been stored refrigerated unopened for 14 months. Therefore we have given this product a one year expiration dating unopened.

The open vial stability for this product when stored at 2-8°C is 6 weeks. Real time open vial studies consisted of removing the control from the refrigerator (2-8°C storage) daily, allowing it to warm to room temperature (18-26°C), removing an aliquot of control, and returning the vial to the refrigerator (2-8°C) for storage. Testing was done on one product lot of each level of control initially and after 2 months of daily opening. The sperm cell counts passed real time open vial refrigerated stability within the originally established control limits of 2 standard deviations, up to 8 weeks. Therefore we have given this product a six week expiration dating after opening.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Susan A. Rothmann, Ph.D., HCLD
President
Fertility Solutions, Inc.
13000 Shaker Boulevard
Cleveland, Ohio 44120

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Re: k041240
Trade/Device Name: AQC™ Sperm Count Quality Controls and
AQC™ Post-Vasectomy Quality Controls
Regulation Number: 21 CFR § 864.8625
Regulation Name: Hematology Quality Control Mixture
Regulatory Class: II
Product Code: NRF
Dated: May 7, 2004
Received: May 11, 2004

Dear Dr. Rothmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Joseph L. Hackett

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041240

Device Name: AQC™ Sperm Count Quality Control, AQC™ Post-Vasectomy Quality Control

Indications For Use: For In Vitro Diagnostic Use

The AQC™ Sperm Count and AQC™ Post-vasectomy Quality Controls are intended for monitoring sperm counts performed either manually using commercially available counting chambers or using computer assisted semen analysis (CASA) instruments. The AQC™ Sperm Count and AQC™ Post-vasectomy Quality Controls are intended for use as Quality Control materials having known sperm concentrations. Daily monitoring of the control values establishes intra-laboratory parameters for accuracy and precision of the cell counting methods. These products are also available for external laboratory quality control and proficiency testing and as such are sold under the proprietary trade names, AQC™ Sperm Count and AQC™ Post-Vasectomy Proficiency Challenges.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

Prescription Use ✓ NO 510(k) AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)